Standard Risk Submission Checklist

To be submitted with Human Research Ethics Application

|  |  |
| --- | --- |
| Study Title:  |  |
| Type of Study (Please tick) \*See definitions below  |
| Clinical Trial Phase 0 | 🞎 | Clinical Trial Phase 1 | 🞎 | Clinical Trial Phase 2 | 🞎 | Clinical Trial Phase 3 | 🞎 | Clinical Trial Phase 4 | 🞎 |
| Clinical Trial Device | 🞎 | Clinical Trial Drug | 🞎 | Clinical Trial Other\* | 🞎 | Clinical Interventional Research Not a Clinical Trial\* | 🞎 | Clinical Trial Surgery/ Procedural Interventions\* | 🞎 |
| Populations Health\* | 🞎 | Mental Health Research\* | 🞎 | Qualitative Research\* | 🞎 | Paediatric | 🞎 | Other Health and Medical Research\* | 🞎 |
| Other (Please Specify) | 🞎 |  |
| Department: |  |
| Is this a Student Project? | 🞎 Yes 🞎 No  | Is this a University driven Project? | 🞎 Yes 🞎 No  |
| Mode of Approval |
| CHQ HREC and Research Governance | 🞎 | CHQ HREC Only | 🞎 | Research Governance Only | 🞎 |
| Single Centre (Please list site) |  | Multi Centre – More than one site external to CHQ (Please list sites) |  |

|  |
| --- |
| Definitions for Types of Studies |
| Clinical Trial Other\* - Studies that do not fall under the broad definitions of drug, surgical or device trials. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, herbal medicines, web-based treatments, motivational classes, music therapy, and stem cell interventions |
| Clinical Interventional Research Not a Clinical Trial\* - Interventional research involving human participants in health and illness done in response to a clinical research question. The aim of such research is to inform clinical practice through the application of patho-physiological, population-based, behavioural or qualitative research methods |
| Clinical Trial Surgery/Procedural Interventions\* - Designed to assess the effect(s) of one or more manual or operative surgical techniques, whether it is in the field of cosmetic, elective, environmental, plastic or replacement surgery (which are performed to diagnose, treat or prevent disease or other abnormal conditions) |
| Population Health\* - Research activities include the collection and analysis of qualitative and quantitative survey data, the analysis of administrative datasets, economic evaluation of health care interventions, healthcare financing priority, evaluation of health services and health policy, studies and knowledge translation. It includes population-level and health-system research but NOT CLINICAL OR BIOMEDICAL RESEARCH |
| Mental Health Research\* - May involve research into the causes and treatment of mental illness or mental disorder. May include therapeutic and non-therapeutic interventions and also includes research involving the disciplined enquiry into mental health promotion including the evaluation of mental health policies or initiatives |
| Qualitative Research\* - Involves disciplined enquiry that examines people's lives, experiences and behaviours and the stories and meanings individuals ascribe to them. It can also investigate organisational functioning, relationships between individuals and groups and social environments. This approach to research can involve the studied use and collection of a variety of empirical materials such as case studies, personal experience, life stories, interviews, observations and cultural texts |
| Other Health and Medical Research\* - Examples may include Human movement and Sports Science; Nutrition and Dietetics; Genetics and Drug and Alcohol |

**Please submit all documentation via ERM and Email (1 Zip file attachment) to** **CHQEthics@health.qld.gov.au**

**Hard copies to be delivered to: Children’s Health Queensland Human Research Ethics Committee
Centre for Children’s Health Research
Level 7, 62 Graham Street
South Brisbane QLD 4101**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Description** | **No. of Paper Copies** | **ERM/EMAIL** |
|  | Standard Risk Submission Checklist Form | 2 | 1 |
|  | Cover letter signed by Principal Investigator including:* Brief description of project, including phase of study if a clinical trial
* List all sites to be approved
* List of supporting documents submitted and confirmation that they have been uploaded to ERM
 | 2 | 1 |
|  | Human Research Ethics Application Form (HREA) completed through [**ERM Website**](https://au.forms.ethicalreviewmanager.com/)  | 2 | 1 |
|  | Parent/Guardian Information Sheets and Consent Forms (from CHQ Templates) | 2 | 1 |
|  | Child/Adolescent Information Sheet (from CHQ Templates) | 2 | 1 |
|  | Protocol | 2 | 1 |
|  | Questionnaires, advertisements, diaries, product information and other patient facing documentation to be used in the study | 2 | 1 |
|  | Victorian Specific Module or Western Australia Module (for applications to be reviewed under MOU) | 2 | 1 |
|  | Radiation Safety Report (if applicable) | 2 | 1 |
|  | Investigator’s Brochure (where applicable) | 1 | 1 |
|  | Indemnity Form consistent with Medicines Australia guidelines where appropriate | 1 | 1 |
|  | Letter of support from CHQ sponsor for external researchers wishing to conduct research within the hospital | 1 | 1 |
|  | Letter of approval from Director of the Department in which the research will be conducted | 1 | 1 |
|  | CV for CPI and Site PIs must be uploaded with the application | 0 | 1 |
|  | Invoicing Fee Form if project is Commercially sponsored |  |  |
| \* | Do all documents contain version numbers, dates and page numbers? |  |  |
| \* | All documents MUST be uploaded to the ERM Website. |  |  |
| \* | Email all documents (as 1 zip file) to CHQEthics@health.qld.gov.au  |  |  |

**If any queries regarding submission requirements, please contact the HREC office:**

**CHQEthics@health.qld.gov.au** **or 3069 7002.**